

REMARKS

Applicants express appreciation to the Examiner for the time spent with applicants' representative discussing the proposed claim amendments and prior art.¹ As presented herein for reconsideration, the claims have been amended as proposed. Specifically, claims 36 – 39, 41 – 45, 48 – 53, 56 – 59, 62 – 66, 68 – 71 and 74 – 77 have been amended.² Six new dependent claims have been added to depend from independent claims 36 and 50, e.g. dependent claims 113 – 115 and 117 – 118, respectively. Thus, by this paper, claims 36 – 39, 41 – 53 and 55 – 77 remain pending (of which claims 36, 50, 64, and 76 are the independent claims) and new dependent claims 113 – 118 are presented.

As noted by applicants in their specification, applicants' invention is directed to a stent for use in various types of vascular procedures. Applicants' stent overcomes a problem which can occur during placement of a stent, in which the stent decreases in length, or foreshortens, along its longitudinal axis as it is expanded when deployed. This foreshortening is undesirable because when deployed, the stent may not span the entire area inside a vessel or orifice that requires expansion and/or support.

As presented herein for reconsideration (see independent claim 64, as exemplary), applicants' invention comprises a tubular body having a longitudinal axis, and having proximal and distal ends and a lumen extending longitudinally therebetween. The tubular body has a wall having areas thereof removed to define a web structure configured for circumferential expansion from a contracted delivery configuration to an expanded deployed configuration. The defined web structure comprises a plurality of web patterns interconnected with one another at a plurality of interconnection locations, and that are arranged so that the web patterns are situated side-by-

¹ Applicants' representative met with the Examiner on Aug. 24th during an in-person interview, as summarized in the Interview Summary of record. A short follow up meeting was conducted with the Examiner on Aug. 26th to confirm that applicants' representative had obtained authorization to amend claims 36 and 50 so that they would contain the same limitations as claims 64 and 76, respectively, so that allowance of generic claims 64 and 76 would also result in allowability of claims 36 and 50, thus removing any further question as to possible restriction of claims 36 and 50. The Examiner indicated that he agreed that claims 36 and 50 would be allowable provided generic claims 64 and 76 are allowed. Applicants' representative also confirmed at the follow up meeting that the Examiner is aware of U.S. Pat. No. 7,141,062 (Pinchasik I). The Examiner confirmed that he was well aware of that reference, and that in fact the disclosure of that patent is already of record as part of the disclosure of U.S. Pat. No. 6,723,119 (Pinchasik III), which is a continuation-in-part of Pinchasik I. The Examiner indicated he is very familiar with the Pinchasik patents since he was the Examiner who issued them. In any event, applicants' representative left a copy of the Pinchasik I patent with Examiner.

² Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

side along the longitudinal length of the tubular body, with each web pattern also extending circumferentially around the wall.

At least one of the interconnected web patterns comprises “at least three webs joined end-to-end so as to extend between a first pair of interconnection locations with no intervening interconnection locations between the first pair of interconnection locations.” The three webs that are joined end-to-end are further defined as “being joined by two bends so that the bends permit the three webs to be generally foldable between the first pair of interconnection locations when said tubular body is in the contracted delivery configuration, and then unfolded when said tubular body is expanded to the deployed configuration.” Lastly, “at least one of said at least three webs [comprises] a plurality of web sections, with one of the web sections being angled relative to one other web section when the stent is in the expanded deployed configuration.”³

In the Office action, independent claim 64 and all of the depending claims (except claim 65)⁴ were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Pat. No. 5,861,027 (Trapp), or in the alternative as obvious over Trapp. Independent claims 36, 50 and 76 and their dependent claims (except claims 39, 41, 53 and 55)⁵ were rejected under 35 U.S.C. § 102(e) as

³ As noted during discussion with the Examiner, the other three independent claims (e.g. claims 36, 50 and 76) are similar.

Claim 36 differs from claim 64 only by adding the further limitation of “a single web connected between a second pair of interconnection locations with no intervening interconnection locations between the second pair of interconnection locations.”

Claim 76 differs from claim 36 only in that the transition locations are defined as transition sections, and by further limiting the last paragraph to recite that “*each web [comprises] three web sections, with one of the web sections being a central section joined at opposite ends thereof to two lateral sections, each of the lateral sections being angled relative to the central section when the stent is in the expanded deployed configuration.*” (Emphasis added and bracketed terms added).

Claim 50 differs from claim 76 by adding the further limitation of “a single web connected between a second pair of interconnection locations defined as transition sections, with no intervening interconnection locations between the second pair of transition sections.”

As discussed with the Examiner, independent claims 64 and 76 are generic to the disclosed embodiments (including Figures 5 and 8A, for example), while independent claims 36 and 50 read more particularly on the embodiment of Figures 8A and 8B. However, claims 36 and 50 should also be allowed for the same reasons as claims 64 and 76, respectively, since claims 36 and 50 only add further limitations to those recited in claims 64 and 76, respectively.

⁴ Claim 65 was rejected as obvious over Trapp as further modified by teachings from U.S. Pat. No. 6,231,600 (Zhong). Claim 65 is patentable for at least the same reasons as noted herein in reference to its independent claim, claim 64.

⁵ Claims 39, 41 and 53, 55 were rejected as obvious over Ballou et al. as further modified by teachings from U.S. Pat. No. 6,117,165 (Becker). Claims 39, 41 and 53, 55 are patentable for at least the same reasons as noted herein in reference to their independent claims, claims 36 and 50, respectively.

anticipated by U.S. Pat. No. 6,071,308 (Ballou et al.), or in the alternative as obvious over Ballou et al.^{6 7}

As discussed at the interview, and as presented herein for reconsideration, the independent claims are not anticipated nor made obvious by Trapp either singly or in combination with any other reference of record. In particular, Trapp discloses a stent which has two principal objects. First, the stent is designed with a structure so that the position of the stent can be precisely determined both during the insertion of the stent and also after the insertion of the stent. Col. 2 lines 61 – 65. This is accomplished by the detection elements (6 in Figs. 1 & 2, 18 in Fig. 4) which are twice the width of the boundary elements 5 surrounding each aperture. Col. 1 lines 38 – 48 and Col. 5 lines 60 – 67. Second, the stent is also designed so that fractures which might otherwise occur in the stent during its expansion and after insertion are prevented.⁸ Col. 3 lines 1 – 3. This is accomplished in Trapp’s design by providing the connection positions 15 (Figs. 4 – 5) with rounded or “broadened portions 16.” Col. 6 lines 61 – 67 and col. 7 lines 1 – 8.

Trapp’s stent includes a tubular body 1 which has apertures 3, 4 (see Fig. 3) cut into the body with a laser. Col. 5 lines 33 – 42. The material of the wall of tubular body 1 lying between the apertures forms boundary elements 5 (see Fig. 4) which surround or “frame” each aperture. See col. 5 lines 53 – 59, col. 6 lines 41 – 45. As shown in Fig. 4 Trapp’s stent has connection positions 15 at each end of each aperture, and above and below each aperture in the middle thereof. Thus, adjacent connection positions 15 in Trapp’s stent are formed by each pair of connection points as defined by one of the connection points located at an end of the aperture and a second connection point located in the middle thereof. Accordingly, half of each boundary element 5 extends between each pair of adjacent connection points at the end and middle of each

⁶ Dependent claims 37, 51 and 77 were additionally rejected as obvious over Ballou et al. as further combined with teachings from Zhong. These claims are patentable for at least the same reasons as their independent claims, e.g. claims 36, 50 and 76, respectively.

⁷ Since the references discussed at the interview and those relied upon in the Office action qualify as “prior” art, if at all, under 35 U.S.C. 102(a)/(e), applicants reserve the right to challenge the status of any reference as qualifying “prior” art. Accordingly, any statement or comment herein to any of the references relied upon in the Office action is made merely for purposes of argument, and assumes *arguendo* that such reference or references are proper qualifying prior art.

⁸ While Trapp notes in the “Description of Prior Art” that “expansion of the stent normally leads to a shortening of the stent in the longitudinal direction and thus to a displacement of at least the stent ends,” Trapp does not address any structural solution to this problem, merely noting that such shortening makes “accurate positioning of the stent

aperture. This means that at most, Trapp's stent provides only two "webs" connected by a single bend between a pair of two and only two connection points 15 (e.g., with no intervening connection point between the pair of connection points 15 located at the end and middle of an aperture).

Moreover, Trapp is further differentiated because both of Trapp's "webs" (e.g., boundary elements 5) which are joined between the pair adjacent connection points 15 are straight, and do not include "a plurality of web sections, with one of the web sections being angled relative to one other web section when the stent is in the expanded deployed configuration" (claims 64 and 36), or "three web sections, with one of the web sections being a central section joined at opposite ends thereof to two lateral sections, each of the lateral sections being angled relative to the central section" (claims 76 and 50).

Thus, Trapp clearly does not anticipate or make obvious applicants' claimed stent (e.g., see claims 36, 50, 64, and 76) which requires, *inter alia*,

- "one or more of the interconnected web patterns comprising *at least three webs joined end-to-end so as to extend between a first pair of interconnection locations with no intervening interconnection locations between the first pair of interconnection locations*" (Claims 36, 50, 64 and 76, emphasis added)
- said *three webs that are joined end-to-end being joined by two bends so that the bends permit the three webs to be generally foldable between the first pair of interconnection locations* when said tubular body is in the contracted delivery configuration, *and then unfolded* when said tubular body is expanded to the deployed configuration." (Claims 36, 50, 64 and 76, emphasis added)
- "*at least one of said at least three webs comprising a plurality of web sections, with one of the web sections being angled relative to one other web section* when the stent is in the expanded deployed configuration" (Claims 64 and 36, emphasis added),⁹ or in the alternative, as claimed in claims 76 and 50 "*each web*

... even more difficult." Col. 2 lines 31 – 38. Thus, while Trapp notes that the problem solved by applicants' claimed stent indeed exists, no solution is presented by Trapp to that problem.

⁹ There was some discussion with the Examiner concerning whether U.S. Pat. No. 6,132,460 (Thompson) discloses the web sections as claimed by applicants. The Examiner suggested that perhaps one could view the webs of Thompson as having sections, but as pointed out by applicants' representative, that is nowhere disclosed by Thompson and indeed seems to clearly be a hindsight reconstruction of Thompson's teaching arrived at in view of applicants' own disclosure. In any event, as acknowledged by the Examiner there clearly is nothing disclosed or suggested in Thompson which teaches or suggests "*one of the web sections being angled relative to one other web section* when the stent is in the expanded deployed configuration," (claims 64 and 36), or "*one of the web sections*

comprising three web sections, with one of the web sections being a central section joined at opposite ends thereof to two lateral sections, each of the lateral sections being angled relative to the central section when the stent is in the expanded deployed configuration.” (Emphasis added).

Accordingly, for at least the reasons noted, independent claim 64 and the claims depending therefrom are neither anticipated nor made obvious by Trapp, either singly or in combination with any other prior art of record, and thus reconsideration and withdrawal of the rejection is respectfully requested.¹⁰

Likewise, independent claims 36, 50 and 76 are not anticipated nor made obvious by Ballou et al., either singly or in combination with any other prior art of record. Ballou et al. describes (see Figs. 1 – 3) a stent that “includes a skeletal frame generally indicated at 2, *formed from a single wire 4*. . . . The *wire 4* includes a plurality of abutting straight portions 6 which are joined to each other, as by welding, *to form closed cell configurations 7* which make up spaced sections or cell segments 9 to form the cylindrical body of the stent when connected together by bridging sections 11.” Col. 2 lines 25 – 35.

Applicants’ claimed stent is comprised of “*a tubular body having a longitudinal axis, and having . . . a wall having areas thereof removed to define a web structure.*” This is completely unlike Ballou et al.’s closed cell, wire stent. Moreover, and in any event, like Trapp, Ballou et al. contains no teaching or suggestion, and thus neither anticipates nor makes obvious applicants’ claimed stent (e.g., see claims 36, 50, 64 and 76), which requires, *inter alia*,

- “one or more of the interconnected web patterns comprising *at least three webs joined end-to-end so as to extend between a first pair of interconnection locations with no intervening interconnection locations between the first pair of interconnection locations*” (Claims 36, 50, 64 and 76, emphasis added)
- said *three webs that are joined end-to-end being joined by two bends so that the bends permit the three webs to be generally foldable between the first pair of*

being a central section joined at opposite ends thereof to two lateral sections, each of the lateral sections being angled relative to the central section when the stent is in the expanded deployed configuration.” (Claims 76 and 50).

¹⁰ Likewise, Trapp also clearly does not disclose a stent that includes in combination (1) the three webs joined end-to-end by two bends between two and only two interconnection locations as noted above, and (2) “*a single web connected between a second pair of interconnection locations with no intervening interconnection locations between the second pair of interconnection locations.*” Thus claims 36 and 50 are also patentable over Trapp, as noted and discussed with the Examiner, for this reason as well.

interconnection locations when said tubular body is in the contracted delivery configuration, *and then unfolded* when said tubular body is expanded to the deployed configuration.” (Claims 36, 50, 64 and 76, emphasis added)

- “*at least one of said at least three webs comprising a plurality of web sections, with one of the web sections being angled relative to one other web section* when the stent is in the expanded deployed configuration” (Claims 36 and 64, emphasis added), or in the alternative, as claimed in claim 50 and 76, “*each web comprising three web sections, with one of the web sections being a central section joined at opposite ends thereof to two lateral sections, each of the lateral sections being angled relative to the central section* when the stent is in the expanded deployed configuration.” (Emphasis added).

Each of the foregoing limitations is completely absent in Ballou et al. Thus, for at least the foregoing reasons,¹¹ the claims as presented herein for reconsideration are patentable over the prior art of record. Indeed, as noted by the Examiner in the Interview Summary the “proposed independent claims 64 and 76, which are generic to the figures disclosed (as for example F. 5 and F. 8A) appeared to define over the art of record. Independent claims 36 and 50, which read on F. 8A, also appeared to define over the art.” Thus, favorable reconsideration and allowance is respectfully requested.

In the event the Examiner finds any remaining impediment to allowance of this application that may be clarified through a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and

¹¹ The arguments herein have focused on the differences between the independent claims and the prior art of record (although as noted herein other references, in particular, Thompson and the Pinachasik patents), were also discussed and are clearly differentiated by the claims as presented. Moreover, emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims, but this does not mean, on the

reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 27th day of August, 2009.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rick D. Nydegger", written in a cursive style.

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